

Genetic Disease Screening Program

November 2013 Estimate

for

Fiscal Years

2013-14 and 2014-15



Department of Public Health

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
BUDGET ESTIMATE OVERVIEW:.....	3
FISCAL YEARS 2013-14 & 2014-15	
BUDGET DETAIL	4
NEWBORN SCREENING PROGRAM	
PRENATAL SCREENING PROGRAM	
FUND CONDITION STATEMENT:	10
FISCAL YEARS 2013-14 & 2014-15	
PROGRAM ASSUMPTIONS AND ESTIMATE METHODOLOGY	11
BACKGROUND	
NEWBORN SCREENING PROGRAM	17
PROGRAM DESCRIPTION AND COST CENTERS	
PRENATAL SCREENING PROGRAM.....	21
PROGRAM DESCRIPTION AND COST CENTERS	

APPENDICES

DEPARTMENT OF FINANCE DEMOGRAPHIC DATA

EXECUTIVE SUMMARY

The 2013 November Estimate includes adjustments in caseload, expenditures, and revenue for the Genetic Disease Testing Fund (0203).

The Genetic Disease Screening Program (GDSP) proposes a reduction in state operations and local assistance expenditure authority for Fiscal Year (FY) 2013-14 of -\$7,105,000 compared to the 2013 Budget Act. Of this amount, -\$3,062,000 is in state operations and -\$4,043,000 is in local assistance. FY 2013-14 local assistance savings includes \$780,000 described in the Estimate cost center detail (beginning on page 3) as well as additional planned savings of \$3,263,000 to properly align expenditure authority with updated revenue projections. The Program continues to research strategies to reduce expenditures. Projections for FY 2014-15 include an increase in local assistance authority of \$907,000 to \$88,654,000.

GDSP estimates total state operations expenditures of \$25,157,000 in FY 2013-14 and \$28,258,000 in FY 2014-15. Total local assistance expenditures of \$83,704,000 in FY 2013-14 and \$88,654,000 in FY 2014-15. As in the past, some fluctuation between budget line items is present due to using the actual prior year average cost per case in conjunction with updated birth data to reflect a more precise expenditure projection.

The GDSP expenditure forecast is based upon the following factors:

- Updated birth data for years 2013 through 2015, derived from the Department of Finance's Demographic Research Unit (DRU). GDSP is using 98% of the DRU birth rate for newborn screening (NBS) and 73% of the DRU birth rate for prenatal screening (PNS) to project program caseload.
- The average cost per case is based on past year actual caseload and expenditures for the following Cost Centers, which are described in further detail in the Estimate package:
 - Contract Laboratories
 - Technical & Scientific
 - Case Management & Coordination Services
 - Reference Laboratories (NBS Only)
 - Follow-up Diagnostic Services (NBS Only)
 - Prenatal Diagnostic Services (PNS Only)
 - Result Reporting and Fee Collection
 - System Project and Maintenance
- Cost Centers are mainly caseload and price driven, with the exception of "System Project" and "Maintenance and Result Reporting and Fee

Collection,” which are impacted by other factors such as IT system maintenance, billing, and shipping costs.

- GDSP is planning to implement a PNS program fee increase of \$45 effective July 1, 2014, bringing the total fee to \$207. This fee increase is necessary to correct for the historic overstatement of caseload and the revenue reductions that resulted from changes to the Medi-Cal reimbursement rate.

NEWBORN SCREENING PROGRAM (NBS)

GDSP expects the NBS program to screen 498,722 newborns in FY 2013-14 and 505,102 in FY 2014-15. The NBS local assistance expenditures are estimated to be \$39,449,242 in FY 2013-14 and \$39,697,367 in FY 2014-15. GDSP is implementing cost containment strategies, and the increase in cost is mainly attributable to an increase in projected caseload.

PRENATAL SCREENING PROGRAM (PNS)

GDSP expects the PNS program to screen 371,497 expecting mothers in FY 2013-14 and 376,249 in FY 2014-15. The PNS local assistance expenditures are estimated to be \$47,517,413 in FY 2013-14 and \$48,956,537 in FY 2014-15. The increase in cost is mainly attributable to increase in projected caseload, and anticipated costs associated with renegotiating contracts with the contract laboratories.

GENETIC DISEASE SCREENING PROGRAM NOVEMBER 2013 BUDGET SUMMARY BY COST CENTER					
Cost Center	2013-2014			2014-2015	
	2013 BUDGET ACT	REVISED November 2013 Estimate	DIFFERENCE	November 2013 Estimate	DIFFERENCE
LOCAL ASSISTANCE					
<u>NBS</u>					
Contract Laboratories:	\$7,614,000	\$7,028,322	(\$585,678)	\$7,117,976	(\$496,024)
Tech & Sci:	\$20,534,000	\$19,865,241	(\$668,759)	\$20,119,363	(\$414,637)
System Project & Maintenance:	\$3,007,000	\$2,807,000	(\$200,000)	\$3,112,000	\$105,000
Case Management & Coordination Services	\$4,544,000	\$4,404,050	(\$139,950)	\$4,237,368	(\$306,632)
Reference Laboratories:	\$2,125,000	\$1,796,262	(\$328,738)	\$1,693,713	(\$431,287)
Follow-up Diagnostic Services:	\$2,087,000	\$1,973,712	(\$113,288)	\$1,842,042	(\$244,958)
Result Reporting & Fee Collection	\$1,575,000	\$1,575,000	\$0	\$1,575,000	\$0
	\$41,486,000	\$39,449,587	(\$2,036,413)	\$39,697,462	(\$1,788,538)
<u>PNS</u>					
Contract Laboratories:	\$4,891,000	\$5,923,267	\$1,032,267	\$6,179,011	\$1,288,011
Tech & Sci:	\$13,384,000	\$12,712,254	(\$671,746)	\$12,874,873	(\$509,127)
System Project & Maintenance:	\$3,130,000	\$3,330,000	\$200,000	\$3,674,825	\$544,825
Case Management & Coordination Services	\$6,088,000	\$6,371,063	\$283,063	\$6,452,563	\$364,563
Prenatal Diagnostic Services:	\$16,741,000	\$17,153,829	\$412,829	\$17,373,266	\$632,266
Result Reporting & Fee Collection	\$2,027,000	\$2,027,000	\$0	\$2,402,000	\$375,000
	\$46,261,000	\$47,517,413	\$1,256,413	\$48,956,537	\$2,695,537
<u>Planned Savings</u>		(\$3,263,000)	(\$3,263,000)		
LOCAL ASSISTANCE, TOTAL	\$87,747,000	\$83,704,000	(\$4,043,000)	\$88,654,000	\$907,000

Genetic Disease Screening Program – Newborn Screening Testing Budget Detail – November 2013¹

COST CENTER: Contract Laboratories

Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 75+ specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of a birth defect or a congenital disorder; a screening test is not diagnostic, additional follow-up is likely to be required for a case that has an initial positive or questionable screening test result. The state contracts with several regional contract laboratories that are paid on a per specimen basis. GDSP will be consolidating the number of regional screening laboratories from seven down to five in FY 2014-15. Competitive procurement may affect the average cost per case.

Fiscal Year	# of Cases	Total Cost	Average Cost Per Case
2012-13	492,427	\$6,939,268	\$14.09
2013-14	498,722	\$7,027,977	\$14.09
2014-15	505,102	\$7,117,881	\$14.09

COST CENTER: Technical & Scientific

Costs are associated with specimen screening include: reagents kits, supplies, processing, and limited maintenance and support (as it directly relates to the reagents) of laboratory equipment that is with the contract laboratories. In addition, there are minimal fixed costs associated with specimen screening including: laboratory supplies, blood specimen filter paper, blood specimen storage, and costs for special packaging for blood specimen transport, etc. Reagent kits, which are the majority of the Technical & Scientific costs, are purchased in lots based on anticipated caseload volume. Reagents vary in cost depending upon the type of screening performed.

Fiscal Year	# of Cases	Total Cost	Average Cost Per Case
2012-13	492,427	\$19,614,497	\$39.83
2013-14	498,722	\$19,865,241	\$39.83
2014-15	505,102	\$20,119,363	\$39.83

¹ These cost estimates do not include Severe Combined Immunodeficiency (SCID) expenditures, as all costs related to this disorder are budgeted under state operations.

COST CENTER: Reference Laboratories

Cases that result in a positive screening test are referred for diagnostic testing at various confirmatory laboratories. Costs include medical and confirmatory diagnostic tests, as well as fixed costs for lab technical support, and expert medical consultation services for rare genetic abnormalities. Reference Laboratories are reimbursed on a cost per test basis.

Fiscal Year	# of Cases	% of NBS Cases	Total Cost	Average Cost Per Case
2012-13	9,704	1.97%	\$1,846,719	\$190.30
2013-14	9,631	1.93%	\$1,796,262	\$186.50
2014-15	9,267	1.83%	\$1,693,713	\$182.77

Average cost per case is expected to decrease as GDSP renegotiates the contracts with reference laboratories. Currently, laboratories receive a fixed amount for providing a base level of services, and a variable fee for certain services. Beginning in FY 2013-14 and through FY 2014-15, these contracts will transition to a strictly fee-for-service basis. GDSP anticipates cost savings as a result of this new contract configuration. Caseload is also anticipated to decrease as GDSP refines the algorithm for detecting positive cases.

COST CENTER: Case Management and Coordination Services

Services provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include: time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS Area Service Centers (ASC) provide critical coordination and tracking services to ensure appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed; this funding supports a required core team of clinical professionals. Costs vary by ASC, dependent upon the geographical location as well as the volume of caseload served.

Fiscal Year	# of Cases	% of NBS Cases	Total Cost	Average Cost Per Case
2012-13	10,988	2.23%	\$4,437,205	\$403.82
2013-14	10,906	2.19%	\$4,404,050	\$403.82
2014-15	10,493	2.08%	\$4,237,369	\$403.82

GDSP anticipates a reduction in the number of cases referred for case management and coordination services in FY 2013-14 due to improvements in the way data is collected and used to detect positive test results. In FY 2014-15, GDSP will be implementing a new algorithm developed in conjunction with the Mayo Clinic that will be more accurate. Ultimately these measures will reduce the number of false positive results and thus the number of infants referred for case management and coordination services.

COST CENTER: Follow-up Diagnostic Services

Follow-up Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination with the NBS ASC and GDSP for ongoing medical care, ensuring the establishment of infant treatment plans through specialty care hospitals and university medical centers specializing in the genetic disorders such as sickle cell anemia, cystic fibrosis, PKU, beta thalassemia, alpha thalassemia, and various neurologic, metabolic, and endocrine disorders, etc. Services are provided through Special Care Centers, which are composed of highly specialized medical teams; cost is based on per case reimbursement.

Fiscal Year	# of Cases	% of Cases	Total Cost	Average Cost Per Case
2012-13	2,449	0.50%	\$2,050,073	\$837.11
2013-14	2,431	0.49%	\$1,973,712	\$811.99
2014-15	2,339	0.46%	\$1,842,042	\$787.63

Average cost per case will decrease in FY 2013-14 due to reduced reimbursement rates that GDSP implemented as a cost containment measure. Costs are anticipated to decrease further in FY 2014-15 due to continued cost containment strategies. Caseload is also expected to decrease as GDSP refines the algorithm for detecting positive cases.

Genetic Disease Screening Program - Prenatal Testing Budget Detail – November 2013

COST CENTER: Contract Laboratories

Laboratory testing to screen pregnant women for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the chance or risk that the fetus has a certain birth defect; the screening provides a risk assessment but not a diagnosis. The state currently contracts with seven regional contract laboratories that are paid on a per specimen basis.

Fiscal Year	Total # of cases	Total Cost	Average Cost Per Case	# of 1st Tri Specimens	Average Cost Per Test	# of 2nd Tri Specimens	Average Cost Per Test
2012-13	358,420	\$4,381,724.00	\$12.23	283,073	\$4.58	344,923	\$9.10
2013-14	371,497	\$5,923,267.49	\$15.94	293,401	\$9.10	357,508	\$9.10
2014-15	376,249	\$6,179,010.88	\$16.42	297,154	\$9.37	362,081	\$9.37

When GDSP added 1st Trimester screening to the PNS program in 2009, the Contract Laboratories agreed to perform testing of 1st Trimester specimens at a reduced rate. That contract expired June 30, 2013. The Contract Laboratories are now paid the same rate for analyzing 1st and 2nd Trimester specimens as shown in the average costs for FY 2013-14. GDSP is in the process of consolidating the seven laboratories down to five and will be going out to bid with the expectation of implementing the new contracts in July 2014. While it is expected that the lab consolidation will yield long term cost savings, it is anticipated that there will be up front fixed costs in FY 2014-15. The lab consolidation is included in this Estimate as a New Major Assumption.

COST CENTER: Technical & Scientific

Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood specimen tubes, laboratory supplies, blood specimen storage, and costs for special packaging for blood specimen transport. Reagent kits, which are the majority of the Technical & Scientific costs, are purchased in lots based on anticipated caseload. Reagents vary in cost depending upon the type of screening performed.

Fiscal Year	# of Cases	Total Cost	Average Cost Per Case	# of 1st Tri Specimens	Average Cost Per Test	# of 2nd Tri Specimens	Average Cost Per Test
2012-13	358,420	\$12,913,466.00	\$36.03	283,073	\$13.73	344,923	\$24.29
2013-14	371,497	\$12,712,253.75	\$34.22	293,401	\$13.73	357,508	\$24.29
2014-15	376,249	\$12,874,872.68	\$34.22	297,154	\$13.73	362,081	\$24.29

COST CENTER: Case Management and Coordination Services

Services provided to pregnant women who screen positive or have questionable results include coordination of first and second trimester screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Area Service Centers (ASC) provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for diagnostic and confirmatory tests, and genetic counseling, and track patients to ensure appointments are kept and patients seen within prescribed timeframes. Coordinators confirm and verify specific patient information as needed with the treating physician offices, and the Prenatal Diagnostic Centers. Costs are fixed for a required core team of medical professionals for the PNS ASC to ensure adequate personnel and infrastructure needs are always in place to provide for all cases referred. Costs associated with these services vary by ASC dependent upon the geographic location and thus the geographic distribution of caseload as well.

Fiscal Year	# of Cases	% PNS Cases	Total Cost	Average Cost Per Case
2012-13	128,155	35.76%	\$6,146,796.00	\$47.96
2013-14	132,831	35.76%	\$6,371,062.65	\$47.96
2014-15	134,530	35.76%	\$6,452,563.17	\$47.96

COST CENTER: Prenatal Diagnostic Services

Women with positive results are provided additional services, which include: confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, and coordination and consultation with patient's physician, and specialty care providers. Services are provided through Prenatal Diagnostic Centers and are reimbursed per service type.

Fiscal Year	# of Cases	% PNS Cases	Total Cost	Average Cost Per Case
2012-13	18,424	5.14%	\$16,550,000.00	\$898.28
2013-14	19,096	5.14%	\$17,153,828.89	\$898.28
2014-15	19,340	5.14%	\$17,373,265.76	\$898.28

GENETIC DISEASE TESTING FUND
FUND CONDITION REPORT
DOLLARS IN THOUSANDS

	2012-13	2013-14	2014-15
RESOURCES			
BEGINNING BALANCE	\$4,517	\$4,459	\$585
Prior Year Adjustment	2,508	-	-
<i>Adjusted Beginning Balance</i>	<u>7,025</u>	<u>4,459</u>	<u>585</u>
REVENUES			
121100 Genetic Disease Testing Fees*	108,225	105,073	121,495
150300 Income from Surplus Investments	12	12	12
161000 Escheat of Unclaimed Checks & Warrants	30	30	30
TOTALS, REVENUES	<u>108,267</u>	<u>105,115</u>	<u>121,537</u>
TOTAL RESOURCES	\$115,292	\$109,574	\$122,122

EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	24,456	25,157	28,258
Planned Savings (State Operations)		[-3,062]	
4265 Department of Public Health (Local Assistance)	86,220	83,704	88,654
Planned Savings (Local Assistance)		[-3,263]	
November Estimate Adjustments (Local Assistance)		[-780]	[907]
0840 State Controller (State Operations)	24	3	-
8880 Financial Information System for California (State Operations)	133	125	-
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	110,833	108,989	116,912

FUND BALANCE	4,459	585	5,210
	4%	1%	4%

REVENUE PROJECTIONS

2013-14							
2013-14 NBS FEES BASED ON	498,722	TESTS @	\$112.70	ANC	98%	=	\$55,081,850
2013-14 PNS FEES BASED ON	204,323	TESTS @	\$152.00	ANC	81%	=	\$25,156,291
2013-14 PNS FEES BASED ON	69,656	TESTS @	\$136.80	ANC	98%	=	\$9,338,320
	<u>97,518</u>	TESTS @	\$152.00	ANC	98%	=	<u>\$14,526,276</u>
	371,497						\$49,020,887
AB 97 Medi-Cal Repayment							\$970,000
GDSP Total							\$105,072,737

2014-15							
2014-15 NBS FEES BASED ON	505,102	TESTS @	\$112.70	ANC	98%	=	\$55,786,473
2014-15 PNS FEES BASED ON	206,937	TESTS @	\$197.00	ANC	81%	=	\$33,020,955
2014-15 PNS FEES BASED ON	<u>169,312</u>	TESTS @	\$197.00	ANC	98%	=	<u>\$32,687,410</u>
	376,249						\$65,708,366
GDSP Total							\$121,494,839

* Revenue Projections for FY 2013-14 includes AB 97 Medi-cal reduction repayment.

GENETIC DISEASE SCREENING PROGRAM ASSUMPTIONS

November 2013

FISCAL YEARS 2013-2014 & 2014-2015

INTRODUCTION

The Genetic Disease Screening Program (GDSP) Estimate is based upon the information outlined in the following pages. The Estimate includes the costs of all major components necessary to administer the program, except state operations. The Estimate is developed in a two-step process: (1) the base is determined and (2) adjustments to the base are applied. The base estimate is the anticipated level of program expenditures assuming that there will be no major changes in program, and is derived from prior year actual caseload and expenditures. Adjustments to the base reflect the expected impacts of program changes that are either anticipated to occur in the current or budget year or have recently occurred and are not fully reflected in the base estimate. The combination of these two estimate components produces the final GDSP Estimate for the Newborn Screening program (NBS) and the Prenatal Screening program (PNS).

Genetic Disease Screening Program

GDSP provides screening of all newborns for genetic and congenital disorders that are preventable or remediable by early intervention. GDSP also provides screening of all pregnant women who consent to screening for serious birth defects. The screening programs provide public education, laboratory, and diagnostic clinical services through contracts with private vendors meeting state standards. The program is fully supported through fees that are collected from screening participants through the hospital of birth, third party payers, or private parties, and are deposited into the Genetic Disease Testing Fund (GDTF). The Medi-Cal Program funds screening services for the eligible population.

Program Summary

The GDSP proposes a reduction in state operations and local assistance expenditures authority for FY 2013-14 of -\$7,105,000 compared to the 2013 Budget Act. Of this amount, -\$3,062,000 is in state operations and -\$4,043,000 is in local assistance. FY 2013-14 local assistance savings includes \$780,000 as described in the Estimate cost center detail, as well as additional planned savings of \$3,263,000 to properly align expenditure authority with updated revenue projections. The Program continues to research strategies to reduce expenditures. Projections for FY 2014-15 include an increase in local assistance authority of \$907,000, to \$88,654,000. The 2013 November Estimate includes adjustments in caseload, expenditures, and revenue for the Genetic Disease Testing Fund (0203).

GDSP estimates total state operations expenditures of \$25,157,000 in FY 2013-14 and \$28,258,000 in FY 2014-15; and, total local assistance expenditures of \$83,704,000 in current year FY 2013-14 and \$88,653,905 in FY 2014-15. Total revenue in FY 2013-14 is estimated to be \$105,072,737, and is estimated to be \$121,494,839 in FY 2014-15.

As in the past, some fluctuation between budget line items is present as a result of using the actual prior year average cost per case in conjunction with updated birth data to reflect a more precise expenditure projection.

Newborn Screening Program (NBS)

GDSP expects the NBS program to screen 498,722 newborns in FY 2013-14 and 505,102 in FY 2014-15. The NBS local assistance expenditures are estimated to be \$39,449,587 in FY 2013-14 and \$39,697,462 in FY 2014-15. GDSP is implementing cost containment strategies, and the increase in cost is mainly attributable to an increase in projected caseload.

The NBS program expects to contain costs through improvements to the algorithm used to identify positive cases. GDSP has worked in tandem with the Mayo Clinic in Rochester Minnesota to refine the methodology by which cases are referred for further confirmation and diagnostic testing, and follow up services. Ultimately these measures will reduce the number of false positive test results.

Prenatal Screening Program (PNS)

GDSP expects the PNS program to screen 371,497 expecting mothers in FY 2013-14 and 376,249 in FY 2014-15. The PNS local assistance expenditures are estimated to be \$47,517,413 in FY 2013-14 and \$48,956,537 in FY 2014-15. The increase in cost is mainly attributable to an increase in projected caseload, and anticipated costs associated with renegotiating contracts with the contract laboratories.

BASE ESTIMATE

Actual caseload and expenditures for the prior year for both the NBS and PNS programs are used to construct the base estimate, and then adjustments are applied to the base.

Cost Centers are mainly caseload and price driven, with the exception of System Project and Maintenance and Result Reporting and Fee Collection, which are impacted by other factors such as IT system maintenance, billing, and shipping costs.

The base level for newborn screening expenditure is established as follows:

- ❑ Number of tests performed by contract laboratories X per test reimbursement.
- ❑ Number of reagent kits used X cost per kit.
- ❑ Number of tests requiring case management services X cost of follow-up for case management centers.
- ❑ Number of tests requiring follow-up, referral, and counseling X cost of follow-up for these tests.

- ❑ Number of referrals to special centers for clinical diagnostic services X cost of follow-up at special centers.

The base level for prenatal screening workload is established as follows:

- ❑ Number of tests by contract laboratories X per test reimbursement.
- ❑ Number of reagent kits used X cost per kit.
- ❑ Number of tests requiring follow-up, referral, and counseling X cost of follow-up for these tests.
- ❑ Number of women referred to Prenatal Diagnostic Centers (PDC) X cost per PDC referral.

The base estimate is the anticipated level of program expenditures assuming there will be no changes in the program as approved in the Governor's Budget. The base estimate is adjusted by projected utilization rates and projected changes in the associated costs of contracts for the laboratory tests, follow up services, counseling, and diagnostic services. Any change in costs is reflected in the fiscal estimates above.

ADJUSTMENTS TO THE LOCAL ASSISTANCE BASE

NEW ASSUMPTIONS

PNS Contract Increase

When GDSP began Integrated Prenatal Screening in 2009, a significantly reduced rate for 1st Trimester screening was negotiated with the seven regional testing laboratories. Those contracts ended in June 2013. The new contracted rates for 1st Trimester screening match the 2nd Trimester contracted rate, resulting in an increase in the PNS Contract Laboratory expenditures of approximately \$1.34 million.

Lab Consolidation

GDSP is in the process of consolidating the seven laboratories down to five and will be going out to bid with the expectation of implementing the new contracts in July 2014. While it is expected that the lab consolidation will yield long term cost savings, it is anticipated there will be up-front costs, including moving expenses, in FY 2014-15. With the consolidation of regional testing laboratories, GDSP anticipates the loss of existing medical courier service that transports specimens from the collection site to the testing laboratory at some of the regional testing laboratories. This service is currently provided at no additional cost to GDSP. In order to ensure timely delivery of specimens to the laboratories, GDSP will need to increase the number specimens it ships to the laboratories via its contract with Golden State Overnight.

Caseload Projection

Historically, GDSP Estimates have overstated NBS caseload. In previous Estimates, NBS caseload was projected as 100% of the Department of Finance Demographic Research Unit (DRU) estimated birth rate for each fiscal year. This estimate methodology did not account for the small portion of the population that opts out of the program. To account for this discrepancy, GDSP has revised its methodology to project NBS caseload. GDSP calculated actual NBS participation rates as a percent of actual births for the most recent three prior years in which actual birth data is available. These three percentages were averaged, and this average was multiplied by the DRU projected birth rate to estimate NBS caseload.

Similarly, the PNS caseloads have been overstated. In previous Estimates, PNS caseload was projected as 80% of the NBS caseload (or 80% of the DRU birth rate). To prevent over estimating the PNS caseload, GDSP adopted a methodology that is similar to the way NBS caseload is now calculated. To estimate PNS caseload, GDSP calculated the actual PNS caseload as a percent of actual births for the most recent three prior years in which actual birth data is available. These three percentages were averaged, and this average was multiplied by the DRU projected birth rate to estimate the PNS caseload.

Actual Caseload as Percent of Actual Births

	Actual Births	PNS Actuals	PNS as % of B.R.	NBS Actuals	NBS as % B.R.
FY 09-10	515,729	372,940	72.3%	509,229	98.7%
FY 10-11	509,531	370,364	72.7%	502,719	98.7%
FY 11-12	503,027	370,231	73.6%	491,119	97.6%
Average			73%		98%

Thus the projected NBS caseload for FY 2013-14 and FY 2014-15 is 498,722 and 505,102 respectively, which is 98% of the DRU estimated birth rate of 508,900 in FY 2013-14 and 515,410 in FY 2014-15.

The projected PNS caseload for FY 2013-14 and FY 2014-15 is 371,497 and 376,249 respectively, which is 73% of the DRU estimated birth rate of 508,900 in FY 2013-14 and 515,410 in FY 2014-15.

Medi-Cal Reimbursement Rate

AB X3 5, Chapter 3, Statutes 2008, reduced Medi-Cal reimbursements to GDSP first by 10% (July 2008 – February 2009) and then was adjusted to a 1% reduction (March 2009 – December 2011). Beginning in January 2012 and continuing through November 30, 2013, AB 97 reduced the Medi-Cal reimbursement rate for laboratory services by 10%. This reimbursement rate reduction resulted in a reduction in the amount of Medi-Cal revenue collected of approximately \$2.6 million in FY 2012/2013 and \$10.2 million since 2008. Starting December 2013, GDSP is no longer subject to the 10% payment reduction from Medi-Cal and anticipates receiving a refund for the period of June 1, 2011 through November 30, 2013 in September 2014.

Fee Increase

GDSP currently collects a participation fee from the patient or her health insurance group. The participation fee covers the blood test for all women and follow-up services offered to women with positive screening results. Medi-Cal covers approximately 45% of the women participating in the PNS Program. Additionally, GDSP must pay \$10 from the fee collected of each PNS participant to the California Birth Defects Monitoring Program (CBDMP) for support of the Prenatal Specimen Biobank.

GDSP is planning to implement a PNS Program fee increase of \$45 effective July 1, 2014, bringing the total fee to \$207. This fee increase is necessary to correct for the historic overstatement of caseload and the revenue reductions that resulted from changes to the Medi-Cal reimbursement rate. Since FY 2010-11, GDSP has not realized sufficient revenue to cover expenditures. This increase will enable the program to maintain the current level of services, account for prior year deficits, and adjust for reductions in Medi-Cal reimbursements.

GDSP: OLD ASSUMPTIONS

None

FUTURE FISCAL ISSUES

None

GDSP: INFORMATION ONLY

None

BACKGROUND

GENETIC DISEASE SCREENING PROGRAM: NEWBORN SCREENING PROGRAM

The mandatory Newborn Screening Program tests nearly every baby born in California for over 75 different congenital and genetic disorders. These disorders cause disability and even death if left undiagnosed and untreated.

Contract Laboratories:

- The newborn's blood sample (specimen) is collected at the hospital prior to discharge on special filter paper, dried, and mailed to a pre-assigned regional screening laboratory contracted by the state.
- Screening tests are carried out at seven (7) contract laboratories located throughout the state. Each specimen is subject to the same routine set of screening panels, regardless of which contract laboratory performs the screening.
- Screening laboratories ascertain the *possibility* of a birth defect or a congenital disorder; a screening test is not diagnostic, therefore additional follow up may be required for a case that has an initial positive or a questionable screening test result.
- Each contract laboratory serves certain County jurisdictions with no duplication, and all counties are served.
- Contract laboratories are compensated on a per-screening panel set basis that is a contract negotiated rate and varies from laboratory to laboratory.
- Laboratory rates vary due to geographical lab locations, Union/non-Union laboratory agreements, as well as the volume of screens performed.

COST CENTER: Expenditures under **Contract Laboratories** reflect the cost of services performed by the contract laboratories to process initial specimen screening.

Technology & Scientific Supplies:

- Screening for genetic abnormalities requires the use of testing reagents to analyze blood specimens.
- GDSP purchases and supplies reagents, test kits, chemicals, and other supplies to the seven contract laboratories, thereby securing the best negotiated price based on large volume purchases.
 - GDSP approximates 3-5% of shelf life expiration, spills, and other wastage (varies depending upon testing equipment and reagent type).
 - Laboratory standard of practice requires regular scheduled standardization of the test and the equipment (positive and negative controls, and spiked test specimens (i.e., unknowns) provided by

GDSP, tested in contract laboratories under real conditions, and reported back to GDSP). This requires approximately 15-20% additional reagent use for standardization testing above and beyond routine specimen testing.

- Reagent costs vary depending upon the type of screening performed. Purchase prices are actively negotiated to secure the best value for the state.
- GDSP maintains inventories that can be used to supply the seven contract laboratories in the event of unforeseen shortages.
- Additional costs associated with specimen screening include laboratory supplies (test tubes, pipettes, etc.), blood specimen storage, as well as costs for special packaging for blood specimen transport.
- The Technology & Science budget also includes fixed costs such as limited maintenance and support of laboratory equipment provided to the seven contract laboratories for required repairs, and maintenance and upgrades in the event the equipment can be serviced and full replacement may be avoided.

COST CENTER: Expenditures under **Technology & Scientific Supplies** reflect costs associated with reagents/supplies necessary to analyze blood specimens.

System Project & Maintenance:

- GDSP maintains a highly complex IT system, the Screening Information System (SIS), which is a web-based application that serves as a tracking mechanism of confidential clinical data for the NBS Program, as well as follow-up services for multiple statewide partners.
- Multiple technical resources are required to assist GDSP with ongoing maintenance and system operations.
- Support of GDSP's IT infrastructure is critical to Program operations; any technical disruptions may bring the Program to a halt or result in unacceptable reporting errors.
- Acquisition of information technology projects may be reflected in this cost center.

COST CENTER: Expenditures in the System Project & Maintenance are for ongoing maintenance and operation costs for the existing IT infrastructure.

Case Management and Coordination Services

- Diagnosis, management, follow-up and counseling are critical components of the Program.
- Positive or equivocal results for newborns with inadequate or untimely specimens are reported to regional NBS Area Service Center (ASC)

contractors, which are strategically located throughout the state within seven regions and are linked electronically to the NBS Program via the SIS.

- The ASC Coordinators provide time-critical case management so that short term follow-up is done as quickly as possible, sometimes within a life-threatening time frame.
- The ASC Coordinators are responsible for notifying the newborn's physician of all questionable results and tracking the cases until follow-up is completed and the case is either ruled out or transferred to a specialized treatment center.
- The ASC is composed of a core team of medical professionals; the cost for each ASC varies depending upon the geographical location as well as the range in volume of caseload served.

COST CENTER: Expenditures in **Case Management & Coordinating Services** reflect costs for a core team of clinical personnel.

Reference Laboratories

- When the initial test result is questionable or positive, the patient is referred for diagnostic testing at a confirmatory laboratory.
- Expert genetic diseases laboratories are contracted by GDSP to perform reference and confirmatory testing for screening positive or equivocal tests.
- Reference Laboratories are reimbursed on a per test compensation basis, with one laboratory doing all confirmatory testing for a particular genetic disorder.

COST CENTER: Expenditures in **Reference Laboratories** reflect costs associated with confirmatory diagnostic testing.

Follow-up Diagnostic Services

- Services are conducted at multiple regional Special Care Centers. These Centers are experts in the specific area of the genetic abnormality and provide extensive monitoring, diagnosis and treatment. Specialty Centers provide case reporting and annual five-year follow-up data to GDSP on diagnosed cases medically managed through the specialty center.
- Health outcome data of infants detected through the program serves as a critical mechanism for tracking, confirmation, evaluation, and refinement of program standards. This data is used to collaborate with other state genetic screening programs to refine identification and treatment as a national benefit.
- GDSP is data driven in its policy and funding allocations. The outcome data of cases initially identified through the program are critical in ensuring the California screening program is a success.

- Having a contractual relationship with a network of specialized medical care centers assures the state that efforts in detecting genetic disorders are not wasted in that once a genetic disorder is detected, a timely and a precise referral process for medical intervention will be initiated to resolve avoidable medical problems as well, as unnecessary costs to the public health care system if the case is not treated.
- Includes coordination with the NBS ASC as well as GDSP for ongoing medical care, establishment of infant treatment plans through specialty care hospitals and university medical centers specializing in a particular diagnosis, such as sickle cell anemia, cystic fibrosis, PKU, beta thalassemia, alpha thalassemia, and various neurologic, metabolic, endocrine and immune disorders.

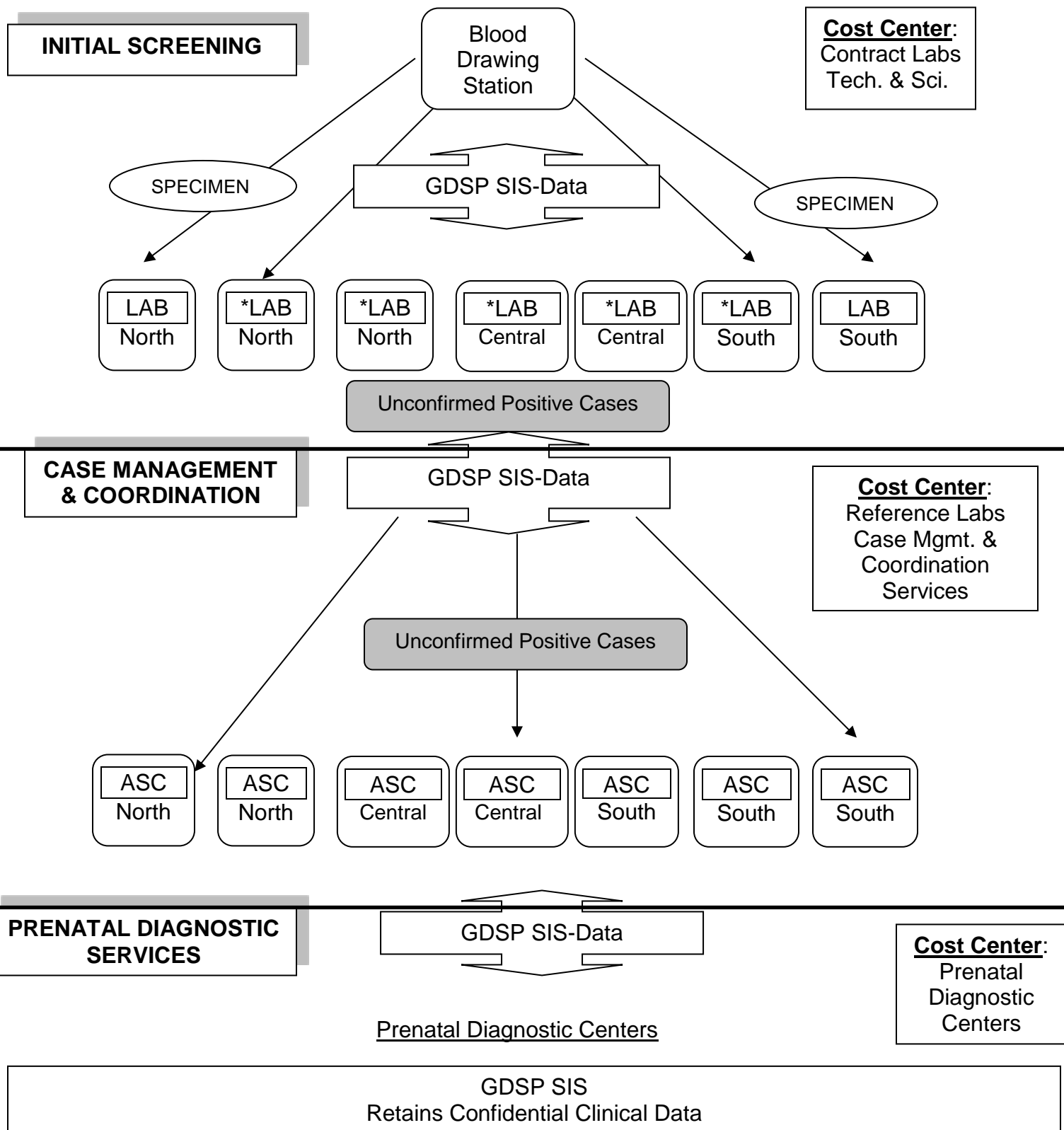
COST CENTER: Expenditures in **Follow-up Diagnostic Services** reflect costs for services on a per-case reimbursement.

Result Reporting & Fee Collection:

- Production expenses associated with communicating results of genetic screens, educational materials, etc. For example, a report of each baby's initial test results, called the Newborn Screening Results Mailer, is mailed to the hospital that drew the specimen as well as to the newborn's physician. If the initial screening test is positive, or if the sample is not adequate for testing, the mailer provides information on follow-up procedures.
- Costs associated with tracking and processing revenue from hospitals and other birthing locations.
- Educational materials developed by the Program and distributed through health care clinics that provide practical information and support to parents. Materials are available at no cost to health care providers, hospitals, clinics, and local health departments.
- Costs related to invoicing and collecting payment from the hospitals and birthing facilities are categorized under this line item.

COST CENTER: Expenditures in **Result Reporting & Fee Collection** reflect costs of reporting results and production of follow-up material to medical providers and families of children as well as costs related to the collection of payments.

PRENATAL SCREENING PROGRAM



* Out of the seven original labs, the five market labs will be consolidated into three. Five total labs will remain after consolidation (the North and South labs and the 3 consolidated labs).

BACKGROUND

GENETIC DISEASE SCREENING PROGRAM: PRENATAL SCREENING PROGRAM

The Prenatal Screening Program (PNS) screens for birth defects during pregnancy and provides risk assessment and follow-up services to all pregnant women in California.

Contract Laboratories:

- GDSP contracts with seven screening laboratories located throughout the state. Screening laboratories ascertain the *possibility* of a birth defect or a congenital disorder; a screening test is not diagnostic, therefore additional follow up may be required for a case that has an initial positive or a questionable screening test result.
- Laboratory testing screens pregnancies for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS) and Neural Tube Defects.
 - **1st Trimester Screening:** Includes testing of human chorionic gonadotropin (HCG) and pregnancy-associated plasma protein A (PAPP-A).
 - **2nd Trimester Screening:** Includes testing of HCG, alpha-fetoprotein (AFP), unconjugated estriol (uE3) and Inhibin.
- Contract laboratories are compensated on a per screening panel set basis that is a contract negotiated rate and varies from laboratory to laboratory.
- Each contract laboratory serves certain County jurisdictions with no duplication, and all counties are served.
- Laboratory rates vary due to fluctuations in geographical areas, Union/non-Union laboratory agreements as well as the volume of screens performed.

COST CENTER: Expenditures under **Contract Laboratories** reflect the cost of services performed by the contract laboratories to process initial specimen screening.

Technology & Scientific Supplies:

- Screening for genetic abnormalities requires the use of testing reagents to analyze blood specimens.

- GDSP purchases and supplies reagents, test kits, chemicals and other supplies to the seven contract laboratories, thereby securing the best negotiated price based on large volume purchases.
 - GDSP approximates 3-5 % of shelf life expiration, spills, and other wastage (varies depending upon testing equipment and reagent type).
 - Laboratory standards of practice require regular scheduled standardization of the test and the equipment (positive and negative controls, and spiked test specimens (i.e., unknowns) provided by GDSP, tested in contract laboratories under real conditions, and reported back to GDSP). This requires approximately 15-20% additional reagent use for standardization testing above and beyond routine specimen testing.
- Reagent costs vary depending upon the type of screening performed. Purchase prices are actively negotiated to secure the best value for the state.
- GDSP maintains inventories that can be used to supply the seven contract laboratories in the event of unforeseen shortages.
- Additional costs associated with specimen screening include blood specimen tubes and laboratory supplies, blood specimen storage, as well as costs for special packaging for blood specimen transport
- The Technology & Science budget also includes fixed costs such as limited maintenance and support of laboratory equipment provided to the seven contract laboratories for required repairs, maintenance, and upgrades in the event the equipment can be serviced and full replacement may be avoided.

COST CENTER: Expenditures under **Technology & Scientific Supplies** reflect costs associated with reagents/supplies necessary to analyze blood specimens.

System Project & Maintenance:

- GDSP maintains a highly complex IT system, the Screening Information System (SIS), which is a web-based application that serves as a tracking mechanism of confidential clinical data for the PNS Program, as well as follow-up services for multiple statewide partners.
- Multiple technical resources are required to assist GDSP with ongoing maintenance and system operations.
- Support of GDSP's IT infrastructure is critical to Program operations; any technical disruptions may bring the Program to a halt.
- Acquisition of information technology projects may be reflected in this cost center.

COST CENTER: Expenditures in the System Project & Maintenance are for ongoing maintenance and operation costs for the existing IT infrastructure.

Case Management and Coordination Services

- Diagnosis, management, follow-up, and counseling are critical components of the Program.
- Services provided by GDSP Area Service Centers (ASC) Coordinators to pregnant women include coordination of First and Second Trimester screens and Neural Tube Ultrasounds, identification of patients whose blood specimens were drawn too early or were inadequate and require additional blood draws.
- Coordination and consultation with patient's physician and specialty care providers is done at this level.
- The ASC Coordinators provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for confirmatory tests, provide some genetic counseling, and track patients to ensure appointments are kept and patients are seen within prescribed timeframes.
- ASC contractors have projected caseloads based on the expected positive rates for various genetic screens for the population tested.
- The ASC is composed of a core team of medical professionals; the cost for each ASC varies depending upon the geographical location as well as the range in volume of caseload served.

COST CENTER: Expenditures in **Case Management & Coordinating Services** reflect costs for a core team of clinical personnel.

Prenatal Diagnostic Services:

- When a PNS screening test is positive, diagnostic services are offered at a state-approved Prenatal Diagnostic Centers (PDC).
- PDCs are composed of a core team of medical professionals and the cost for each PDC varies depending upon the geographical location as well as the volume in caseload served.
- Diagnostic services, such as comprehensive genetic counseling, Chronic Villus Sampling, Ultrasound, Amniocentesis, etc., are provided to women with positive results as a method of ruling out the estimated chance of a birth defect.
- The PDCs are reimbursed on the basis of services performed.

COST CENTER: Expenditures in **Prenatal Diagnostic Services** reflect costs for services performed for pregnant women with screen positive test results.

Result Reporting & Fee Collection:

- Production expenses associated with communicating results of the prenatal screens and educational materials. If the initial screening test is positive, or if

the sample is not adequate for testing, a GDSP mailer provides detailed information on follow-up procedures.

- Costs associated with tracking and processing payment from women who participated in the Program.
- Educational materials developed by the Program and distributed through health care clinics provide practical information and guidance. Materials are available at no cost to health care providers, hospitals, clinics, and local health departments.
- Costs related to invoicing and collecting payment from the hospitals and birthing facilities is also categorized under this line item.

COST CENTER: Expenditures in **Result Reporting & Fee Collection** reflect costs for production of follow-up material as well as resources for payment collection.

TABLES 1 and 2: CALIFORNIA BIRTHS BY AGE OF MOTHER AND AGE-SPECIFIC FERTILITY RATES

TABLE 1: CALIFORNIA BIRTHS BY AGE OF MOTHER								TABLE 2: AGE-SPECIFIC FERTILITY RATES							
	Age 15-19	Age 20-24	Age 25-29	Age 30-34	Age 35-39	Age 40-44	Total	Age 15-19	Age 20-24	Age 25-29	Age 30-34	Age 35-39	Age 40-44	TFR	
1990	70,951	159,405	183,221	133,423	54,471	10,195	611,666	70.77	134.71	134.91	96.93	44.26	9.48	2.46	
1991	71,793	158,779	177,685	133,192	56,654	11,125	609,228	72.34	134.14	133.85	95.77	44.84	9.90	2.45	
1992	70,867	155,065	171,429	133,205	58,660	11,612	600,838	70.20	131.42	131.12	95.59	45.08	10.22	2.42	
1993	70,091	149,047	163,372	131,438	58,505	12,030	584,483	68.55	127.64	128.41	94.72	44.37	10.45	2.37	
1994	69,885	140,172	154,779	129,926	59,550	12,722	567,034	67.10	122.29	124.27	94.15	44.87	10.87	2.32	
1995	68,284	132,607	148,653	127,853	60,577	13,252	551,226	64.47	118.38	120.18	94.15	45.38	11.15	2.27	
1996	64,603	127,431	145,885	125,030	61,836	13,843	538,628	59.62	115.39	117.08	93.94	45.99	11.41	2.22	
1997	61,107	122,924	141,259	121,938	62,674	14,272	524,174	54.94	110.27	112.19	92.51	46.20	11.44	2.14	
1998	59,207	121,317	140,418	121,326	64,210	14,787	521,265	51.83	107.90	110.77	92.91	47.05	11.59	2.11	
1999	57,615	120,270	137,701	121,779	65,532	15,176	518,073	49.38	105.94	109.13	93.75	47.33	11.67	2.09	
2000	56,273	122,604	139,629	127,516	68,693	16,570	531,285	47.43	106.97	111.44	95.86	49.41	12.40	2.12	
2001	53,779	123,236	136,449	127,957	68,835	17,117	527,372	46.60	104.02	113.37	94.86	49.85	12.18	2.10	
2002	50,947	123,065	137,250	130,379	69,879	17,725	529,245	43.84	101.96	111.92	95.27	50.65	12.45	2.08	
2003	50,042	123,822	140,566	134,819	72,669	18,910	540,828	40.74	99.00	112.72	97.64	52.02	12.79	2.07	
2004	50,436	124,318	141,621	134,592	74,589	19,129	544,685	39.25	97.64	115.04	102.43	54.77	13.59	2.11	
2005	50,777	125,541	143,463	133,760	75,740	19,418	548,700	38.79	96.32	114.80	104.08	56.35	13.78	2.12	
2006	53,455	1	148,287	133,462	77,793	20,007	562,157	38.50	96.20	114.37	105.21	56.99	14.16	2.13	
2007	54,060	127,996	150,523	135,376	78,453	19,729	566,137	40.00	98.16	115.89	106.16	58.24	14.82	2.17	
2008	52,332	122,281	147,071	132,616	76,962	20,304	551,567	39.88	96.98	115.12	107.64	58.67	14.80	2.17	
2009	48,362	113,942	140,972	129,089	74,488	19,922	526,774	38.27	92.11	109.61	104.20	58.28	15.46	2.09	
2010	43,584	107,664	136,837	128,895	72,962	20,031	509,974	35.34	85.44	103.52	99.32	57.72	15.27	1.98	
2011	38,754	103,017	134,289	132,375	72,980	20,608	502,023	32.03	80.07	100.08	97.86	57.03	15.36	1.91	
Projection:								Projection:							
2012	39,010	102,746	134,373	135,668	72,594	20,635	505,027	28.62	76.44	98.18	100.62	57.05	15.85	1.88	
2013	39,801	106,850	136,273	136,380	74,742	20,984	515,029	29.91	73.45	97.11	103.17	56.74	15.92	1.88	
2014	41,140	107,008	136,741	138,541	75,462	21,078	519,969	30.83	74.55	97.23	102.60	58.57	16.37	1.90	
2015	41,645	103,820	137,785	141,015	77,855	21,057	523,178	32.11	74.67	96.08	103.24	59.11	16.66	1.91	
2016	41,912	100,827	139,708	142,368	79,664	20,976	525,455	32.54	72.97	95.45	104.36	60.74	16.88	1.91	
2017	41,929	98,816	144,557	146,254	82,586	21,391	535,534	32.71	71.84	93.57	103.31	61.01	16.62	1.90	
2018	41,801	96,984	147,463	150,624	84,925	21,803	543,601	32.60	71.53	94.09	103.97	61.97	16.74	1.90	
2019	42,308	95,438	146,682	153,093	86,022	21,808	545,351	32.38	71.09	95.72	105.99	63.21	17.16	1.93	
2020	42,219	94,411	146,924	155,390	87,106	21,796	547,845	32.66	70.83	94.95	106.66	63.54	17.25	1.93	
2021	41,988	93,457	146,071	157,832	88,176	21,780	549,304	32.48	70.93	94.83	107.21	63.86	17.33	1.93	
Source:	Historical births through 2011, California Department of Public Health, Center for Health Statistics.														
	Projected births, California Department of Finance, Demographic Research Unit.														
Rounding:	Independent rounding may prevent the sum of selected data components from exactly matching the total.														